DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 21, 2014

Olympus Winter & Ibe GmbH
% Graham Baillie
Regulatory Affairs
Olympus Surgical Tech. America
136 Turnpike Road
Southborough, MA 01772

Re: K142525
Trade/Device Name: PK Lap Loop
Regulation Number: 21 CFR 884.4150
Regulation Name: Bipolar Endoscopic Coagulator-Cutter and Accessories
Regulatory Class: Class II
Product Code: HIN
Dated: September 5, 2014
Received: September 10, 2014

Dear Graham Baillie,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -A

Benjamin Fisher
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
PK Lap Loop

Indications for Use *(Describe)*
The Bipolar Laparoscopic Loop PK Lap Loop is a 5mm bipolar electrosurgical device. The device is intended to be used for the amputation of the mobilised uterus during Laparoscopic Supracervical (Subtotal) Hysterectomy and the resection of devascularized subserosal pedunculated myomas. It is used in conjunction with the Olympus Electrosurgical Generator ESG-400.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

PK Lap Loop

510(k) Premarket Notification

510(k) Summary

Olympus Winter & Ibe

510(k) Summary of Safety and Effectiveness

General information

Applicant:	Olympus Winter & Ibe GmbH Kuehnstrasse 61 22045 Hamburg Germany
Establishment Registration No.:	9610773
Manufacturer:	Olympus Winter & Ibe GmbH Kuehnstrasse 61 22045 Hamburg Germany
510(k) Submitter:	Gyrus ACMI, Inc. Olympus surgical Technologies America (OSTA) 136 Turnpike Road Southborough, MA 01772 Phone (508) 804-2738 Fax (508) 804-2624 Establishment Registration No. 3003790304
Official Correspondent:	Graham Baillie Regulatory Affairs Manager Phone: 508.804.2738 Fax: 508.804.2624 Email: Graham.baillie@olympus-osta.com
Contact person:	Mr. Holger Nadler Phone: +49-66966-2860 Fax: +49-66966-2134 Email: holger.nadler@olympus-oste.eu
Date Prepared:	August 29th, 2014
Trade Name:	Pk Lap Loop

Device identification

Proprietary name:	PK Lap Loop
Device Classification name:	Coagulator-Cutter, Endoscopic, Bipolar (And Accessories)
Regulation Medical Specialty:	Obstetrics/Gynecology
Regulations Number:	21 CFR 884.4150
Regulatory class:	Class II
Product code:	HIN

Predicate device

K122605: PKS BILL

Description of device

The Bipolar Laparoscopic Loop is a single use disposable high frequency RF bipolar accessory to be used in conjunction with the Olympus Electrosurgical Generator ESG-400. It is available in an 88mm x 227mm loop size. The device is sterile for single use sterilized by ethylene.

Intended use

The bipolar Laparoscopic Loop PK Lap Loop is a 5mm bipolar electrosurgical device. The device is intended to be used for the amputation of the mobilised uterus during Laparoscopic Supracervical (Subtotal) Hysterectomy and the resection of devascularized subserosal pedunculated myomas. It is used in conjunction with the Olympus Electrosurgical Generator ESG-400.

Comparison of the technology between the PK Lap Loop and PKS BiLL

The technical characteristics are listed below

Compatibility		
Electrosurgical Generator	For PK Lap Loop the RF is delivered through the Olympus ESG 400 generator and the PKS BiLL energy is delivered through the Gyrus G400	different
Energy used and delivered	Identical output waveforms and power levels are used in both devices.	identical
Compatibility with other devices	Same as PKS Bill. Device not to be activated at the same time as other electrosurgical devices.	identical
Design		
Design	The design of the PK Lap Loop device is fundamentally the same as PKS BiLL. There are minor changes that have no impact upon safety, usability and performance.	similar
Technical Data		

Performance	The performance of the PK Lap Loop device in use with the ESG400 generator is the same as PKS BILL in use with the Gyrus G400 generator. This considers tissue effect, speeds and forces required to complete the amputation.	identical
Device Minimum and Maximum output powers	Average power of one cycle period is 200W.	identical
Cutting time	<15 seconds max.	
Electrode dimensions	88mm x 227mm	identical
Loop wire diameter	0.4mm single wire	identical
To fit tocar	5mm	identical
Safety		
Electrical safety	Both devices are compliant with IEC 60601, IEC 60601-1, IEC and 60601-2-2	identical
Electrical Safety	Meets IEC 60601-1, IEC 60601-2-2	identical
Thermal safety	Both devices are compliant with the relevant clauses of IEC 60601.	identical
Biocompatibility	All materials for PK Lap Loop are the same as used in the construction of PKS BiLL with the exception of the insulation on the main shaft. Note: whilst it is described as insulation, the function is purely cosmetic and therefore it has been omitted from the PK Lap Loop design. The majority of the patient contact materials have been used on other devices. The coated wires and nylon insulators successfully completed an additional cytotoxicity test following EtO sterilization to ensure that materials are compliant to ISO10993.	similar
Mechanical safety	Both devices are designed to withstand the same clinical loads. The clinical inputs apply to both devices as they have the same function and intended use.	identical
Sterility/Methodology	The PKS Bill is gamma irradiated, the PK Lap Loop is ETO sterilized	different
Sterility/Assurance level	PK Lap Loop and PKS Bill have both a sterility assurance level of 10 -6	identical

Performance Data

Performance data were created to demonstrate substantial equivalence with the predicate device PKS Bill.

The verification and validation activities involved mechanical and tissue tests as well as electrical safety, biocompatibility and sterilization testing according to FDA recognized standards.

Interface tests to demonstrate compatibility to the Electro Surgical Generator ESG-400 were performed during this submission.
The technical justification report comprises the device requirements not needing additional tests to demonstrate substantial equivalence and can be adopted from predicate device.

The Lap Loop is compliant to electrical standards specifically to those applicable sections of IEC 60601-1:2005/(R)2012 and 60601-2-2:2009 Edition 5.0 incorporating electrical, thermal safety and Electromagnetic Interference.
Biocompatibility testing was completed on the predicate PKS BiLL and therefore is used to leverage the PK Lap Loop device given the commonality of patient contact parts. As an additional measure, Cytotoxicity tests on all patient contacting parts have been performed in compliance to the relevant requirements of ISO 10993:2009.
It is packaged and sterilized as a sterile single use device tested according to FDA recognized consensus standards ISO 11607 (11607-1:2006/(R)2010 and 11607-2:2006 First edition) and 11737 (11737-1:2006 Second Edition and 11737-2:2009 Second Edition).

Technological features and Substantial Equivalence

The PK Lap Loop Instrument is substantially equivalent to the predicate which is currently marketed as PKS BiLL cleared under K122605. The principles of function, operation, fundamental scientific technology, and physical dimensions of the PKS Lap Loop Instrument are identical to the predicate PKS Bill device.
The PK Lap Loop is a copy of its predicates PKS Bill (K122605) in construction and mechanical design. Compared with its predicates the PK Lap Loop is operated by the Olympus Electrosurgical Generator ESG-400 (K141225). The predicate PKS Bill is driven by the Gyrus Electrosurgical Generator G400, (K081954). Both Generators provide identical waveforms and power levels as demonstrated during the 510(k) submission K141225.
As well as the Gyrus Generator G400 the ESG-400 uses a universal socket with a self-recognition system. The socket detects the specific PK-Instument to provide only the proper allowable range of waveform output and power level.
The design of the PK Lap Loop device is fundamentally the same as PKS BiLL. There are minor changes as a result of corporate branding from Gyrus ACMI to Olympus. These minor changes have no impact upon safety, usability and performance.

The PK Lap Loop has the same intended use as the FDA cleared PKS Bill. It is intended to be used for the amputation of the mobilised uterus during Laparoscopic Supracervical (Subtotal) Hysterectomy and the resection of devascularized subserosal pedunculated myomas when used with the Olympus Electrosurgical Generator.
Also the intended population of patients remains the same (Laparoscopic Patients).
There is a change of Indications of Use. The PK-instrument is renamed from PKS-Bill to PK Lap Loop and the PK Lap Loop is used in conjunction with the Olympus Electro Surgical Generator ESG-400 (cleared under K141225).

The facts summarized:

- The Lap Loop and predicate PKS BiLL (K122605) are identical products when considering the Bipolar PK (Plasma Kinetic) technology and mechanical design features.
- The PK Lap Loop is compatible to the Olympus Generator ESG-400 (K141225).

- The Olympus Generator ESG-400 (K141225) provides identical output waveforms and power levels as the FDA cleared Gyrus G400 electrosurgical generator, K081954.
- Just like the predicates PKS Bill (K122605 and K111059) the Lap Loop contains device recognition. It ensures that the PK Lap Loop can only be connected to the Olympus Generator ESG-400 (K141225). The plug is very different and poke yoked to preclude a connection to another generator. The Olympus specific Multifunctional Connector delivers the correct range of waveforms and power levels at the output socket.

The Lap Loop uses materials that are well established and used in other Olympus Winter & Ibe GmbH and GYRUS ACMI FDA cleared medical devices. This also involves the blue ring which is integrated in the shaft and the new cable for use with the ESG400 generator for Corporate Design reasons.
Refering the biocompatibility the materials for PK Lap Loop are all the same as used in the construction of PKS BiLL.

The PK Lap Loop device will be manufactured at the same facility as the predicate device using common procedures.

Summary

The bipolar Laparoscopic Lap Loop, as described in this submission, is substantially equivalent to the predicate in intended use, materials, principles of operation and fundamental scientific technology and raises no new issues of safety and effectiveness.